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Fisher

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(54) **IMPLANTABLE SLING SYSTEMS AND METHODS**

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See application file for complete search history.

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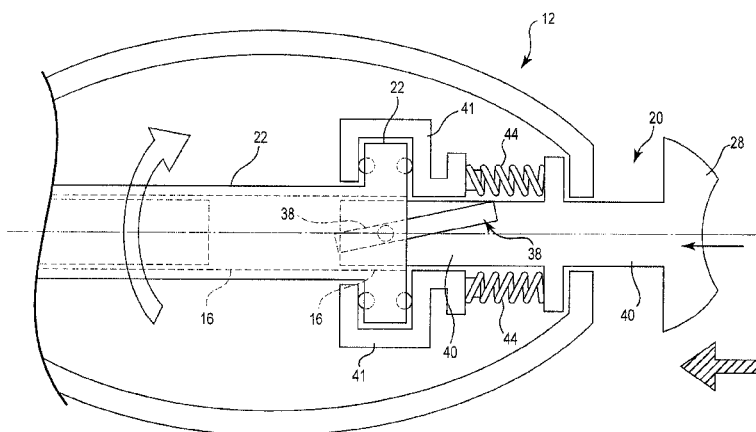
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(57) **ABSTRACT**

Various embodiments of sling or implant systems are provided. The sling or implant systems can be employed to treat incontinence, prolapse, and like conditions. A needle delivery device can be included, wherein the delivery device includes a needle and a rotatable sheath. The rotatable sheath can rotate upon actuation relative to the needle to selectively deploy or disengage an implant anchor from the distal end of the needle.

20 Claims, 9 Drawing Sheets



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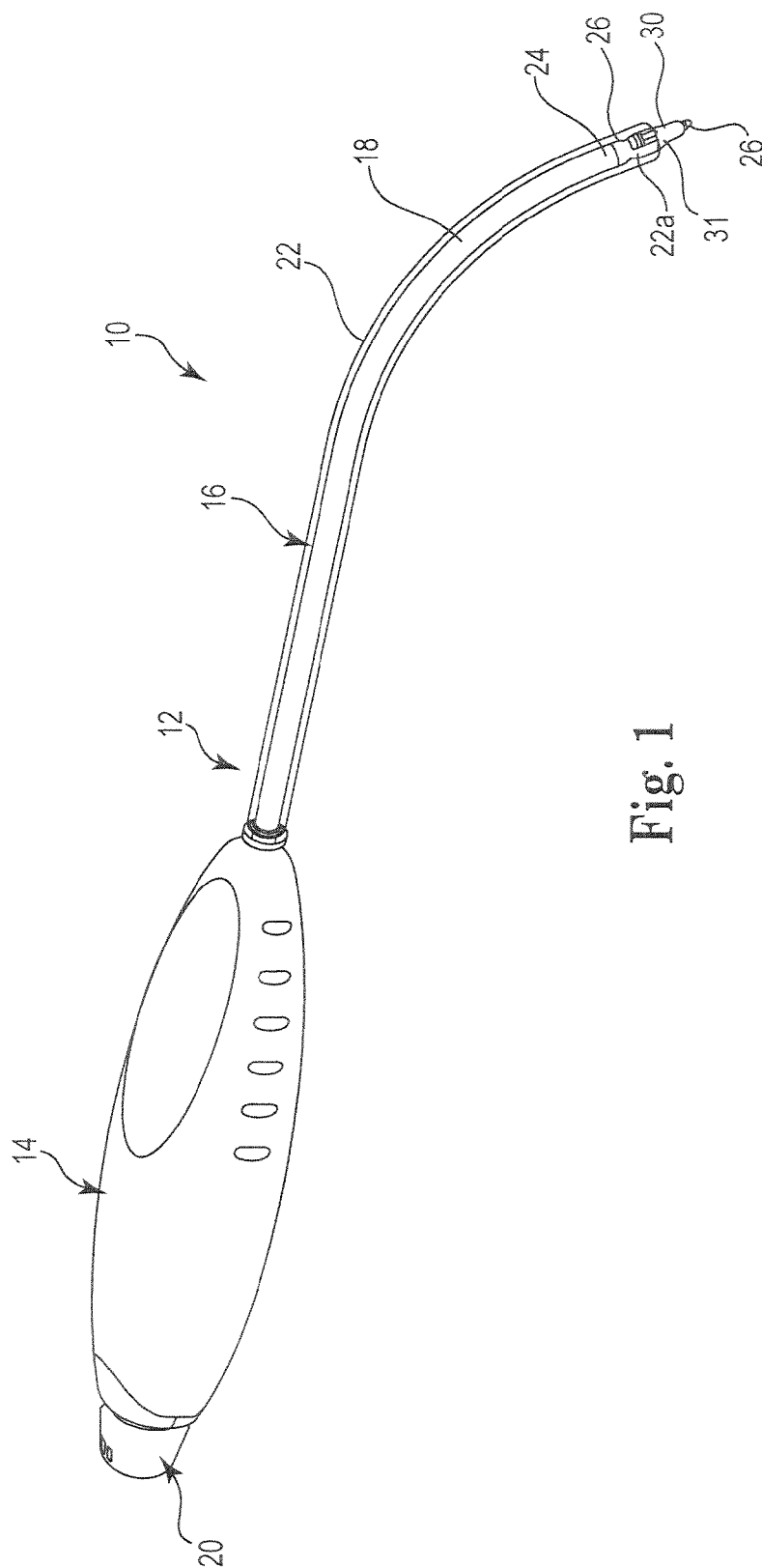


Fig. 1

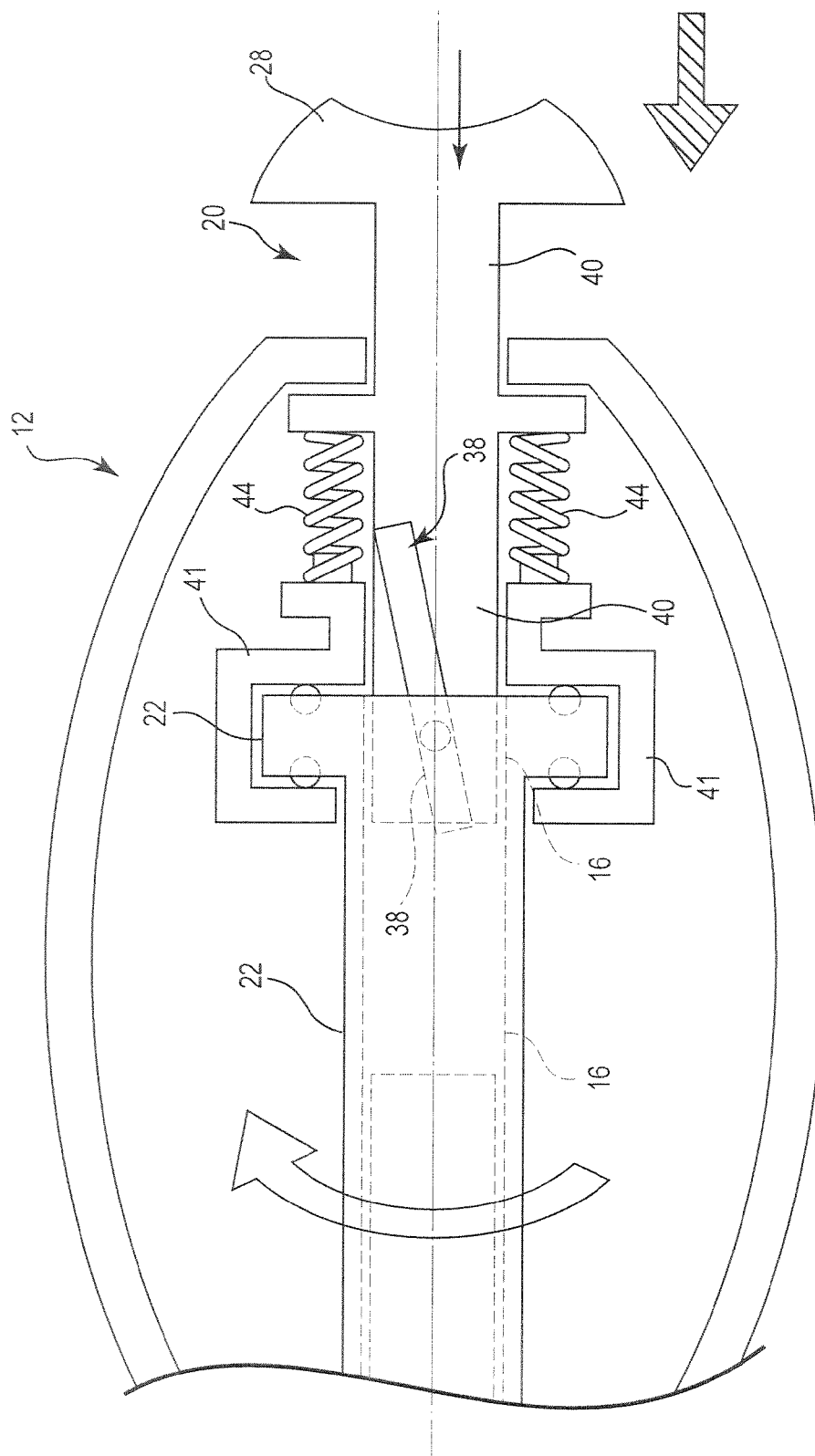


Fig. 2

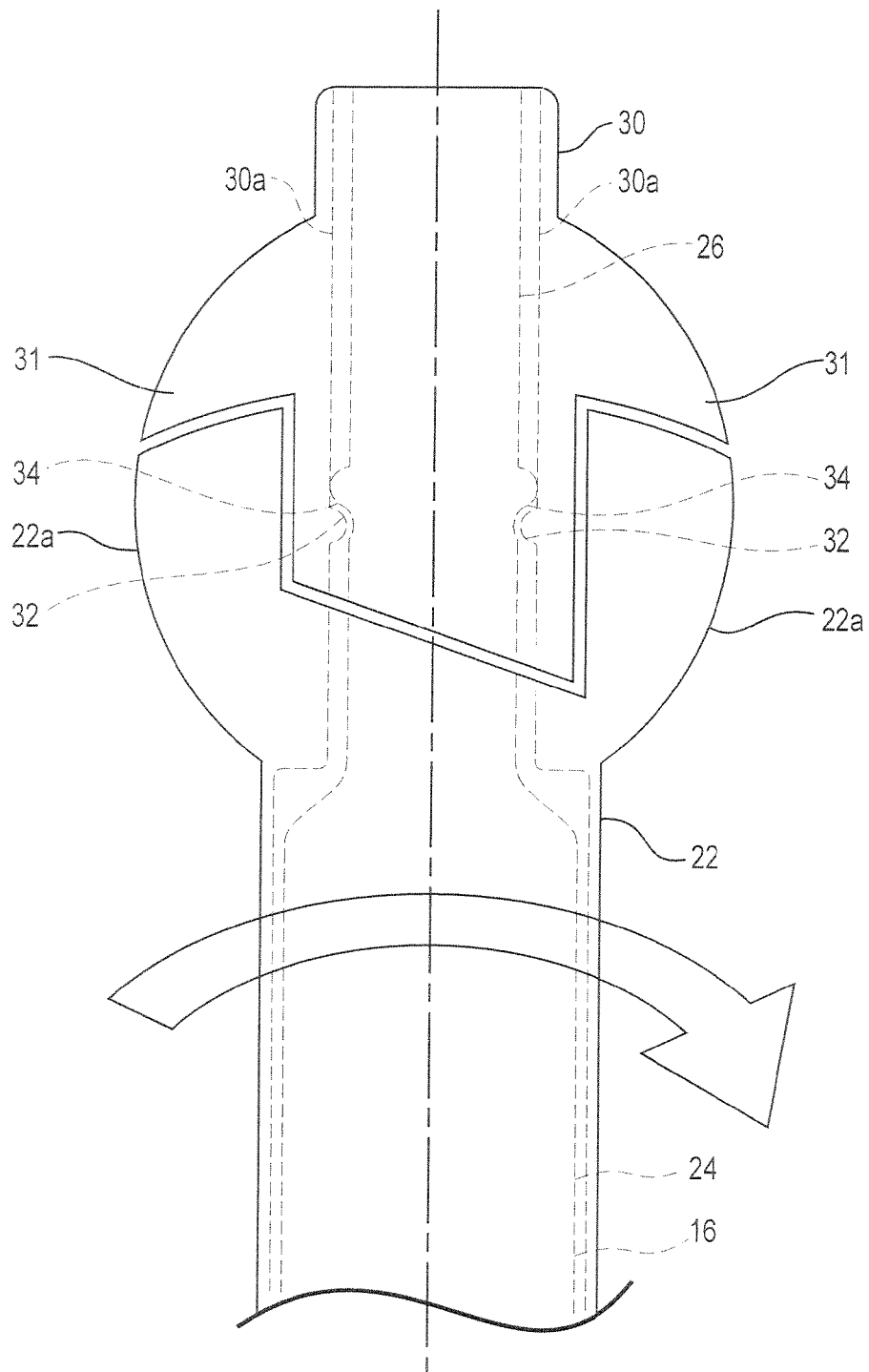


Fig. 3

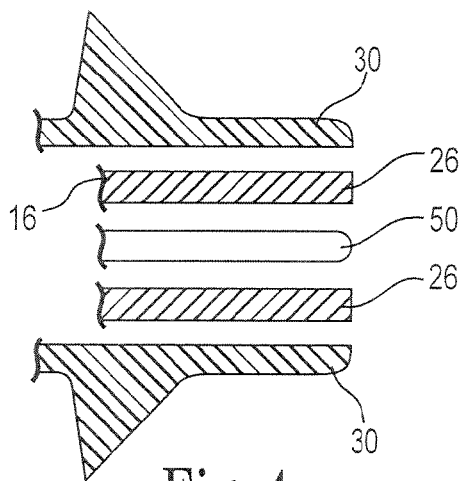


Fig. 4

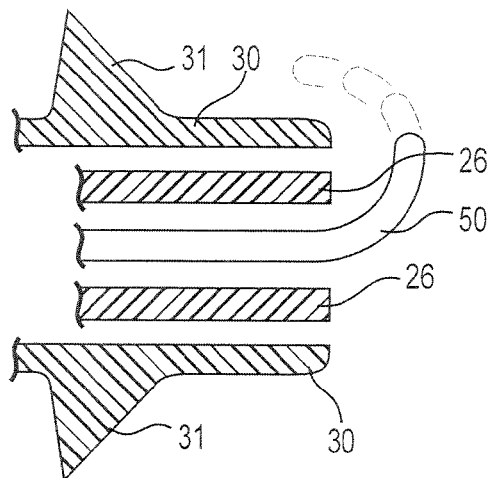


Fig. 5

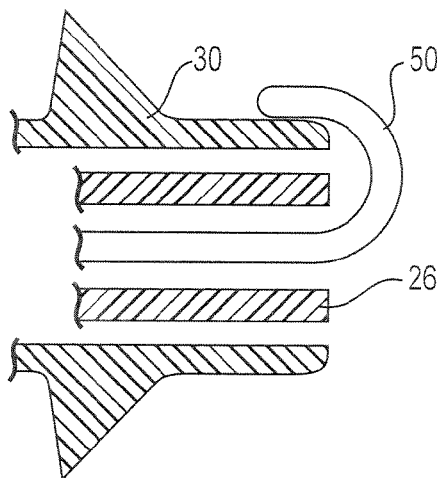
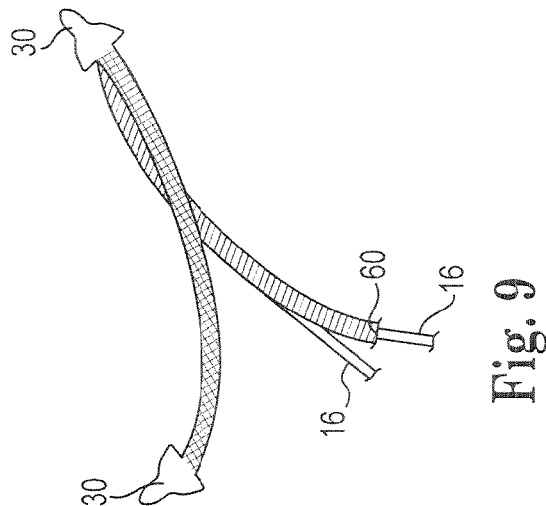
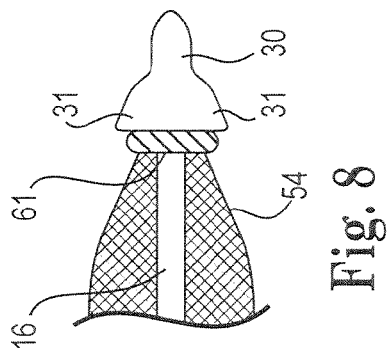
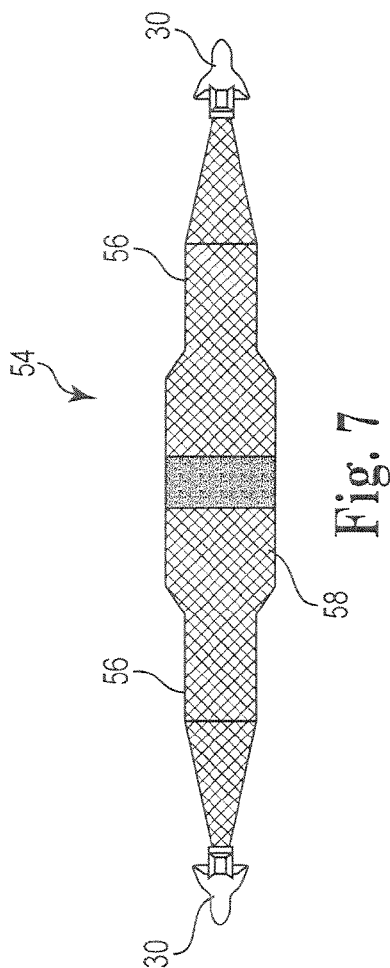


Fig. 6



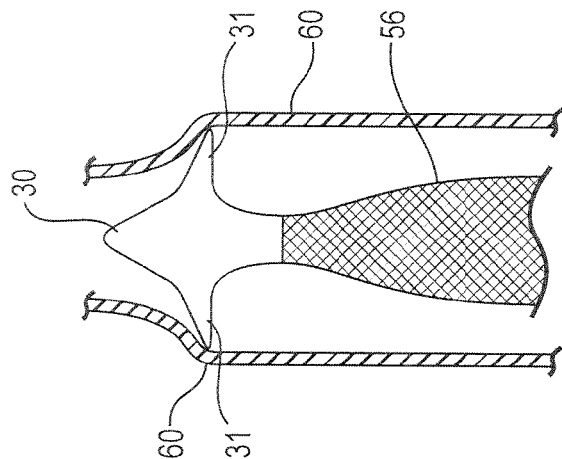


Fig. 11

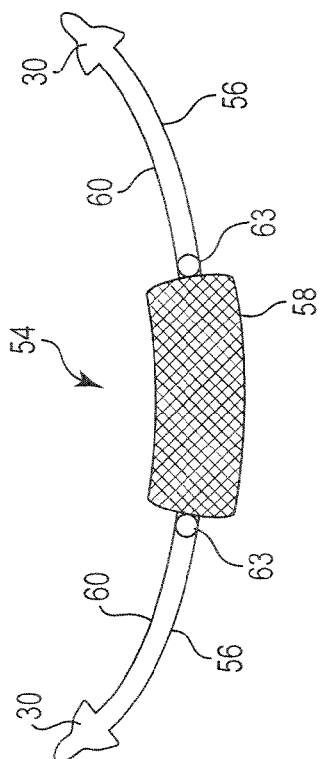


Fig. 10

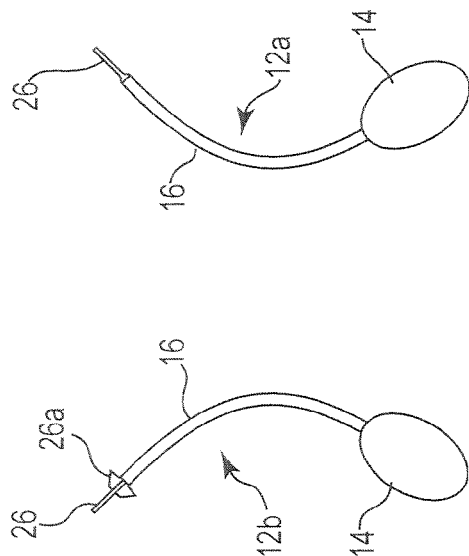


Fig. 13

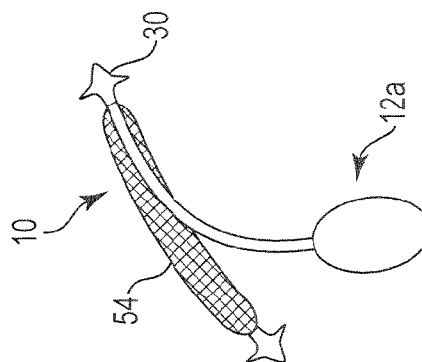


Fig. 15

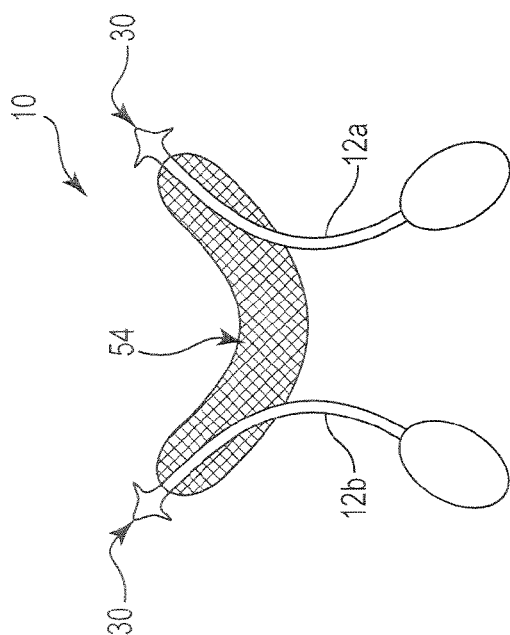


Fig. 12

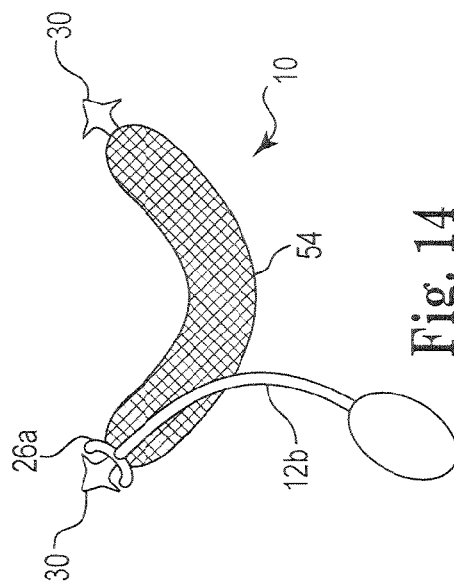


Fig. 14

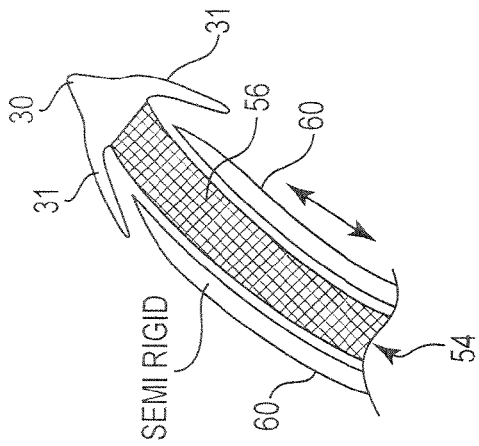


Fig. 16

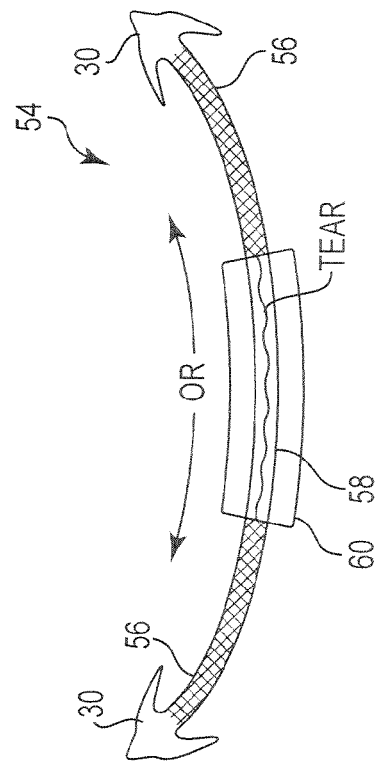


Fig. 17

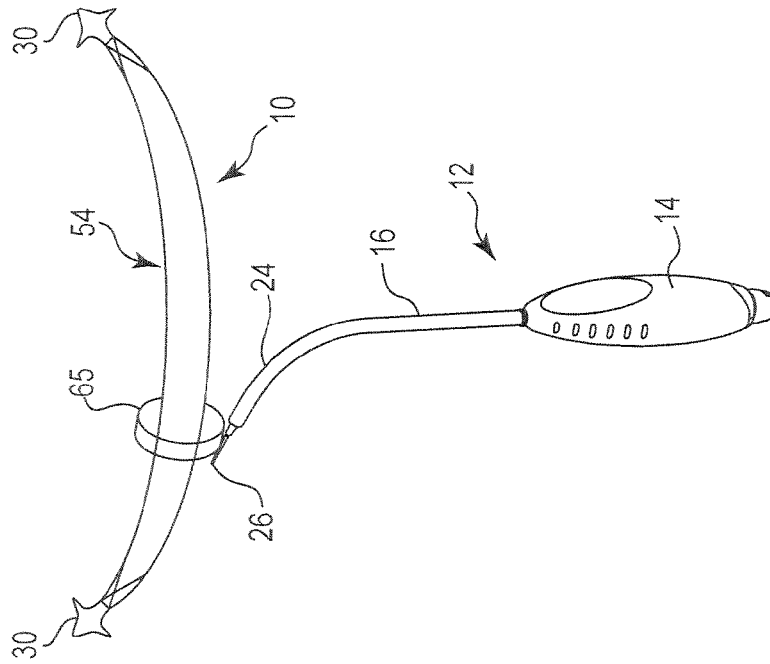


Fig. 18

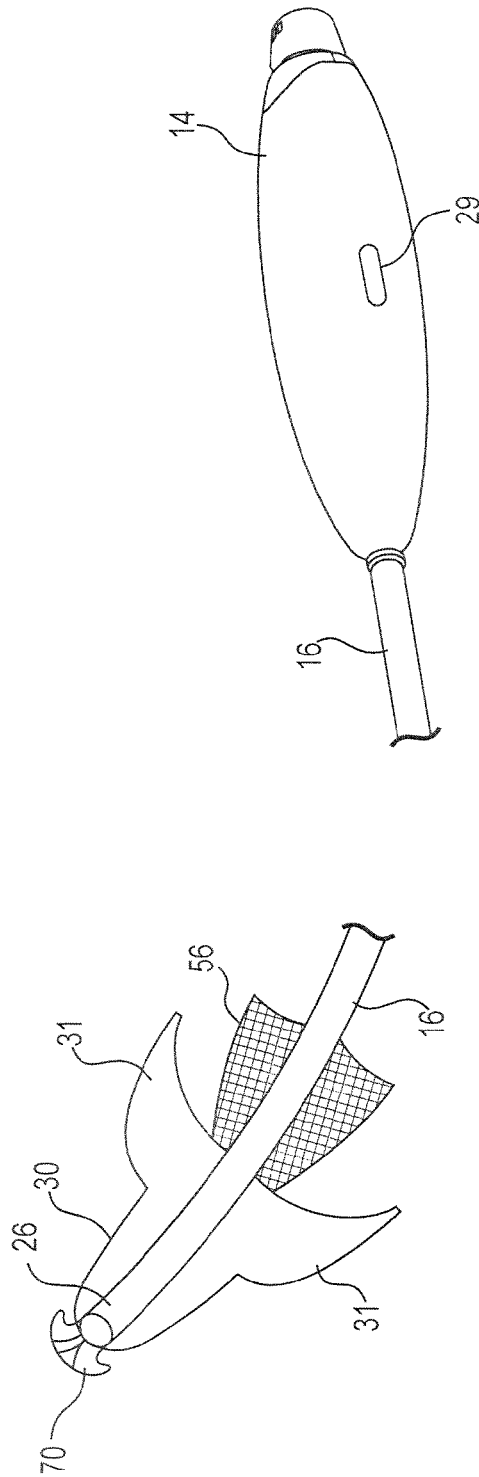


Fig. 19

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IMPLANTABLE SLING SYSTEMS AND METHODS

PRIORITY

This application claims priority to and the benefit of U.S. Provisional Application Nos. 61/291,210, filed Dec. 30, 2009, 61/291,372, filed Dec. 31, 2009, and 61/291,363, filed Dec. 31, 2009; wherein each of the referenced applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

The present invention relates generally to surgical methods and apparatus and, more specifically, to surgically implantable mesh or sling devices and methods for using and deploying the same.

BACKGROUND OF THE INVENTION

Pelvic health for men and women is a medical area of increasing importance, at least in part due to an aging population. Examples of common pelvic ailments include incontinence (e.g., fecal and urinary), pelvic tissue prolapse (e.g., female vaginal prolapse), and conditions of the pelvic floor.

Urinary incontinence can further be classified as including different types, such as stress urinary incontinence (SUI), urge urinary incontinence, mixed urinary incontinence, among others. Other pelvic floor disorders include cystocele, rectocele, enterocele, and prolapse such as anal, uterine and vaginal vault prolapse. A cystocele is a hernia of the bladder, usually into the vagina and introitus. Pelvic disorders such as these can result from weakness or damage to normal pelvic support systems.

Urinary incontinence can be characterized by the loss or diminution in the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or female stress urinary incontinence (SUI) generally occurs when the patient is physically stressed.

In its severest forms, vaginal vault prolapse can result in the distension of the vaginal apex outside of the vagina. An enterocele is a vaginal hernia in which the peritoneal sac containing a portion of the small bowel extends into the rectovaginal space. Vaginal vault prolapse and enterocele represent challenging forms of pelvic disorders for surgeons. These procedures often involve lengthy surgical procedure times.

Urinary incontinence can be characterized by the loss or diminution in the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or female stress urinary incontinence (SUI) occurs when the patient is physically stressed.

There is a desire to obtain a minimally invasive yet highly effective implantable mesh that can be used to treat incontinence, and/or pelvic organ prolapse and other conditions.

SUMMARY OF THE INVENTION

The present invention describes pelvic mesh implants and methods for treating pelvic conditions such as incontinence (various forms such as fecal incontinence, stress urinary incontinence, urge incontinence, mixed incontinence, etc.), vaginal prolapse (including various forms such as enterocele, cystocele, rectocele, apical or vault prolapse, uterine descent, etc.), and other conditions caused by muscle and ligament weakness.

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Embodiments of the systems can include one or more needle delivery devices and an implant. The implants can be elongate sling devices, or pelvic prolapse implants. Each implant can generally include a support portion, one or more extension or arm portions, and one or more end anchors. One or more portions of the slings or implants can be constructed of a mesh material.

Various embodiments of the systems can include a needle delivery device having an actuation mechanism and rotatable sheath. The rotatable sheath can shroud or otherwise be provided along at least a portion of the curved or straight needle of the delivery device, and in operable communication with the actuation mechanism. Engagement or activation of the actuation mechanism rotates the sheath to selectively disengage or deploy the anchors of the implant from a distal tip of the needle device.

Certain embodiments of the implant and delivery device can include tube, sheath or like docking or re-docking features to facilitate selective engagement and deployment of the anchor and implant from the device. The anchors can be adapted to penetrate and engage in selected target tissue within the pelvis proximate, at, adjacent, or lateral the urethra, vagina, obturator foramen, endopelvic fascia, bladder, pelvic floor, elevator muscles, and the like.

Embodiments of the present invention may be incorporated into or provided with various commercial products marketed by American Medical Systems of Minnetonka, Minn., e.g., the MiniArc® or MiniArc® Precise Sling Systems.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a needle delivery device with a rotatable sheath in accordance with embodiments of the present invention.

FIG. 2 is a schematic close-up cross-sectional view of a portion of a needle delivery device handle and actuation mechanism in accordance with embodiments of the present invention.

FIG. 3 is a schematic close-up cross-sectional view of a portion of a needle delivery device distal end, anchor and rotatable sheath in accordance with embodiments of the present invention.

FIGS. 4-6 are schematic cross-sectional partial views of an anchor, distal needle tip, and retention feature in accordance with embodiments of the present invention.

FIG. 7 is a top view of a mesh sling implant in accordance with embodiments of the present invention.

FIGS. 8-9 are schematic views of a sling implant, and tube docking/re-docking features or portions in accordance with embodiments of the present invention.

FIG. 10 is a top view of sling implant having a mesh support portion, and extension portions or arms in accordance with embodiments of the present invention.

FIG. 11 is a close-up partial schematic view of a tube or sheath extending substantially around a sling implant and anchor in accordance with embodiments of the present invention.

FIGS. 12-15 show a sling implant and delivery system having multiple needle delivery devices in accordance with embodiments of the present invention.

FIG. 16 is a close-up partial cross-sectional schematic view of a slidable tube or sheath, implant and anchor in accordance with embodiments of the present invention.

FIG. 17 shows a sling implant system having a slidable or displaceable tube or sheath in accordance with embodiments of the present invention.

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FIG. 18 shows a sling implant system having a sling implant, sliding yoke, and needle delivery device in accordance with embodiments of the present invention.

FIG. 19 shows a needle delivery device and distal needle tip configuration in accordance with embodiments of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention generally provides a sling or implant system 10 adapted for insertion to selectively deploy one or more implants or slings to treat various pelvic conditions, including incontinence (e.g., fecal or urinary), pelvic organ prolapse (e.g., rectal or vaginal), or other like conditions. The systems 10 of the present invention can include delivery devices, implants, docking/re-docking features and like configurations, features and devices to facilitate deployment and sling implantation.

The various systems, features and methods detailed herein are envisioned for use with or can incorporate devices, portions or methods of known pelvic implants, tissue or organ repair systems (e.g., for male and female), including those disclosed in U.S. Pat. Nos. 7,500,945, 7,407,480, 7,351,197, 7,347,812, 7,303,525, 7,025,063, 6,691,711, 6,648,921, and 6,612,977, International Patent Publication Nos. WO 2008/057261 and WO 2007/097994, and U.S. Patent Publication Nos. 2010/0105979 2010/0261955, 2002/151762 and 2002/147382. Accordingly, the above-identified disclosures are fully incorporated herein by reference in their entirety.

Referring generally to FIGS. 1-3, embodiments of an implant delivery system 10 are shown. The implant delivery system 10 can include a delivery tool 12, having a handle 14 and a needle portion 16. The handle portion 14 can include an actuation mechanism 20. The needle portion 16 can include a needle 18, a rotatable sheath or tube 22 and a distal end portion 24. In various embodiments, the needle 18 can be hollow, solid, curved, straight, helical, or can take on a myriad of other like and compatible configurations. The sheath 22 generally shrouds a length of the needle portion 16. The distal end portion 24 can include an anchor retention and deployment tip 26.

The actuation mechanism 20 can include a button, slider or like actuator 28 in operable communication with at least the sheath 22 such that engagement or activation of the button 28 will cause the sheath 22 to rotate about the needle 16. FIGS. 2-3 show an embodiment of the handle 14 and distal end portion 24 of the needle 16, wherein pressing on or actuation of the button 28 rotates the sheath 22 to correspondingly deploy, push or release a tissue anchor 30 from the needle portion 16. For retention (e.g., snap engagement) of the anchor 30 on the distal tip 26 of the needle portion, embodiments of the anchor 30 can include small protrusions, ribs, ridges, indents or other features 32 within the lumen 30a of the anchor 30. Corresponding, reversed or mirrored features 34 can be included at the end of the engaged distal tip 26. Snap engagement of the anchor 30 to the tip 26 is provided with the features 32, 34 such that the anchor 30 is retained on the needle portion 16 until the time of selective disengagement during final deployment within the patient's soft tissue. This configuration further allows for audible and tactile feedback of engagement of the anchor 30 to the tip 26. The level of force needed to snap engage anchor 30 and needle 16 can vary greatly, depending on the materials used for the components, and the construct of the features 32, 34. As depicted in FIG. 3, the anchor 30 is initially keyed to the needle body (e.g., tip 26) such that the anchor 30 cannot rotate, but can slide longitudinally.

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The sheath 22 can include a barb guard 22a at the end proximate or at the distal end 24. The barb guard 22a and anchor 30 interface can be angled, straight, undulating, or take on various other configurations to facilitate the described snap engagement or retention. The anchor 30 can include one or more tines 31 adapted to mateably or abutably engage corresponding surfaces or extensions in the barb guard 22a.

The actuation mechanism 20 within the handle 14 can include a cam or follower mechanism 38 causing the sheath 22 to rotate around the needle shaft, such that the anchor 30 is caused to move longitudinally in a distal direction off of the end of the tip 26. This longitudinal distal force on the anchor 30 by the cam mechanism 38 can be sufficient to overcome the retention force of the anchor 30 with the needle in accordance with the anchor retention features described herein. As such, once the retention features are disengaged, the anchor 30 slides freely from its distal position on the needle tip 26 and is thereby deployed.

Referring to FIG. 2, actuation mechanism 20 within the handle can include a barrel 40 adapted for longitudinal displacement within the handle 14 housing. In general, the barrel 40 is restricted from rotational movement. A proximal end of the sheath 22 is constrained within a housing boundary 41 such that it can rotate, but does not move longitudinally. As such, longitudinal movement of the button 28 and barrel 40 causes the sheath 22 to rotate. For example, the sheath 22 can include one or more cam mechanisms or features 38, generally opposed by 180 degrees. The barrel 40 can further include one or more cams, generally opposed by 180 degrees. Compression springs 44 are included and provide a resetting feature.

Various advantages of the embodiments depicted in FIGS. 1-3 include, a self-resetting handle mechanism 20, a convenient handle actuator 28, anchor tines 31 retained until deployment, minimization of tissue disruption by anchor tines 31 during anchor deployment, repeatable and secure engagement and disengagement of the anchor 30 and the needle 16, as well as tactile and audible feedback with the anchor 30 engagement. The various features and mechanisms, or portions thereof, can be constructed of known and compatible metals and polymers.

Referring generally to FIGS. 4-6, selective engagement and retention of the anchor 30 to the needle tip 26 for various embodiments are shown. Such embodiments can include a selectively extendable and retractable fixation member 50. The fixation member 50 is adapted to traverse, generally longitudinally, within or along the lumen of the hollow needle body 16. The fixation member 50 can be a shape memory wire or member, such as a Nitinol or other like wire materials, adapted to move in and out of the distal tip portion 26 of the needle 16 upon actuation by an end user (e.g., button or actuator in the handle 14). Various handle 14 and actuation members 28 can be included in operable communication with the member 50 to facilitate displacement of the member 50.

While traversing within the needle 16, or along an outer portion of the needle in alternative embodiments, the member 50 is retained in a generally longitudinal configuration or shape (FIG. 4). As a portion of the member 50 is deployed out of the distal tip 26 of the needle 16, at least a portion of the member 50 is generally free to resume its default shape, such as a curved or angled configuration. As such, the tip or end portion of the member 50 will tend to move or curve around the distal tip 26 to engage or otherwise retain the anchor 30 attached or provided at the distal tip 26 (FIG. 5). This will, in turn, secure the anchor 30 to the distal tip 26 such that the anchor 30 can be inserted, positioned and ultimately fixated within a target tissue site (FIG. 6).

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Upon reaching the desired target tissue site, the anchor **30** can be released from the distal tip **26** of the needle **16**. Namely, the user can retract or otherwise activate the member **50** such that the member **50** retreats or retracts back toward or into the needle tip **26**. At this point, the needle **16** can be retracted, leaving the tissue anchor **30** in place or fixated to the target tissue site.

Referring generally to FIGS. **7-19**, various embodiments of implantable sling or implant systems **54** are provided. In general, the implant **54** can be a mesh or patterned strut construct having extending portions **56** and a support portion **58**. One or more anchors **30** can be included at the end portions of the extension portions **56**. Various portions of the implants **54** can be constructed of polymer materials, such as a film or sheet material of polypropylene, polyethylene, fluoropolymers or like compatible materials.

Referring generally to FIGS. **8-19**, various embodiments of the mesh or sling implant **54** are shown with various docking or re-docking features. Such re-docking features facilitate repositioning of the anchor **30** with the introducer needle **16**, in or out of the patient's body. In one embodiment, a tube or sheath **60** is provided such that the introducer needle **16** is insertable within the tube **60**. The tube **60** may encircle the needle **16**, it may be integral with the sling or implant **54**, or even made from the mesh or other portion of the implant **54**. In other instances, the tube **60** can be a separate component, and may be semi-circular, v-shaped, or u-shaped rather than completely encircling the needle **16**, to at least partially guide the needle **16** along the tube **60**. The tube **60** can be removed with an axial tensile pull or with relative rotation (e.g., similar to a plastic bottle cap). As shown in FIG. **8**, the tear away portion can include a thin tab **61** adapted to break the anchor **30** away from the needle **16** and/or tube **60** with a twisting motion.

The needle **16** can generally provide a counter force to the twist or rotation to ensure the anchor **30** position is not changed. Further, a barb guard can be included at a distal portion of the tube **60**. The barb guard can provide a guard to prevent the tines **31** of the anchor **30** from engaging tissue until the moment of deployment, and can further serve to abut or provide a slight press fit with the anchor **30**. The tube **60** provides a convenient, consistent and stable means of engagement or docking the needle **16** with the anchors **30** or sling **54**.

The tube or sheath **60** can be torn away after positioning of the anchor **30** and deployment within target tissue. This can be done bilaterally for the two tubes **60**, e.g., both extension portions **56** or end anchors **30**. Perforations, slots, grooves, and like configurations can be included with the tube **60** to facilitate this tear away feature. The needle **16**, or a portion thereof, can be inserted into an end of the hollow tube **60**, or can be guided along an external surface or portion of the tube **60** (both shown in FIG. **9**)

As detailed, the guide sheath or tube **60** can extend from the implant **54** to provide a channel or groove path for the needle to engage the anchors **30**. The guide tube **60** can be constructed in a c-shaped, u-shaped, v-shaped or similar configuration to facilitate guidance of the needle. The tube **60** can be weakly attached (e.g., tear away bonds or welds) to the mesh implant **54** such that the tube **60** can be selectively torn away or otherwise removed from the implant.

The embodiment of FIG. **10** can include an implant **54** having the center mesh support portion **58**, with lateral arms or extension portions **56** extending therefrom. The lateral arms **56** can be included with the tube **60** to again facilitate engagement and guidance of a needle **16** to the anchors **30**. The lateral arms **56** can be constructed of wrapped mesh, hollow tube material, or take on a myriad of other configura-

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tions and material constructs. The arms **56** can further include one or more ports **63** adapted to facilitate entry and exit of the needle **16** or tip **26** for engagement and deployment of the anchor **30**.

As shown in FIG. **11**, various sheath or tube **60** embodiments can extend above or around at least a portion of the anchors **30**. As such, the tube **60** can be longitudinally moved to slide away from the anchors **30** at deployment or implantation. The tube **60** can be perforated or scored to further facilitate removal. Again, the tube **60** can protect the barbs or tines **31** of the anchor **30** from engaging tissue until final implantation.

Referring to FIGS. **12-15**, the sling or implant system **10** can include two needle delivery devices **12** rather than a single needle device. The needle device **12** can be adapted to engage and manipulate a corresponding anchor **30** of the implant **54**. As such, deployment, manipulation, and tensioning can be applied to the implant **54** by one or both of the needle devices. In one embodiment, as shown in FIGS. **11-15**, one of the needle devices **12a** can include a barb guard **26a**, with the other device **12b** not having a barb guard. The needle device **12a** can be used to anchor the sling on a second target tissue location, thus facilitating tensioning (advancing and retracting needle/anchor) without engaging the barbs **31** of the anchor **30** with the tissue until the desired tension is obtained.

In various embodiments, the anchors **30** can include pivotable, moveable, expandable or collapsible tines **31**. In an initial insertion stage, the tines **31** lay generally flat or substantially angled toward the implant **54** or anchor **30** body to prevent engagement of the tines **31** with tissue. Upon deployment, the tines **31** can be forceably or automatically extended out to facilitate engagement with the target tissue location. Expansion and retraction of the tines **31** can be achieved by suture releases, or mechanical or manual means. The anchor **30** or tines **31** can be constructed of acceptable or known materials (e.g., shape memory) and constructs to facilitate such moveable or collapsible functionality.

Referring to FIGS. **16-17**, the tube or sheath **60** can be free floating or adapted to split along a length thereof to facilitate guidance of the needle **16** and moveability of the tube **60**. The tube **60** can be constructed of flexible, rigid, or semi-rigid materials known by those of skill in the art. As such, the tube **60** can selectively engage and disengage with the tines **31** of the anchors **30**. The moveability of the tube **60** allows it to slide along a length of the sling **54** as shown in FIG. **17**, thus facilitating easy removal and optimal positioning during deployment.

As shown in FIG. **18**, the implant system **10** can include a yoke **65** adapted to slide or move along a length of the implant **54** or sheath **60**. Again, the implant **54** can be constructed of mesh, solid material, hollow polymer, and the like. The needle device **12** is adapted to engage the yoke **65** to facilitate attachment with the implant **54** and guidance along the implant **54** and needle **16** during insertion and deployment.

A distal tip **26** of the needle **16** for various embodiments can be elongated to a level that promotes extending out from the lumen in the anchor **30**, for holding or securing sutures, and the like. Sutures can be used for docking and alignment of the mesh ends **56** of the implant **54**, and can be constructed of a relatively stiff material (e.g., wire, coated suture, semi-rigid polymer, etc.). Parts of the suture may need to remain flexible, portions of the suture can be flexible, while others are rigid or semi-rigid.

Further, the anchors **30** of the implant system **10** can include threading (e.g., female) adapted for twisting/rotating engagement with corresponding threads (e.g., male) in the

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distal tip **26** of the needle device **12**. An actuator, rod, or similar mechanism, in the device **12** can facilitate selective threadable engagement and disengagement of the needle tip **26** with the anchors **30**.

The needle device of FIG. **19** can include a distal portion having a bulbous or generally mushroom-shaped element **70** to selectively retain the anchor **30** on the needle tip **26**. As such, an actuator **29** in the handle **14** can be activated or engaged to retract or withdraw the element **70** into the needle **16** lumen to release the anchor **30** from the needle tip during deployment. The element **70** can be generally deformable to permit retraction into and extension from the anchor **30** or other device.

As detailed herein, the anchors **30** can include pivotable or otherwise collapsible tines **31**. The tines **31** can be in communication with the inner lumen **30a** of the anchor **30**, such that when the needle tip **26** is inserted into the lumen, the tines **31** pivot or collapse to facilitate insertion of the implant **54**. At the point of deployment, the needle and tip **26** is removed, thereby causing the tines **31** to return or spring back to their extended position to facilitate fixation and tissue engagement. Pin, rod, or other flexibility or pivot features can be provided with the anchor tines **31** and anchor **30** in general to facilitate the described and depicted collapsibility and expandability.

The implant systems **10**, their various components, structures, features, materials and methods may have a number of suitable configurations as shown and described in the previously-incorporated references. Various methods and tools for introducing, deploying, anchoring and manipulating implants to treat incontinence and prolapse as disclosed in the previously-incorporated references are envisioned for use with the present invention as well. Further, the system and its components or structures can be constructed of known and compatible materials known to those skilled in the art, including metals, polymers, and the like.

All patents, patent applications, and publications cited herein are hereby incorporated by reference in their entirety as if individually incorporated, and include those references incorporated within the identified patents, patent applications and publications.

Obviously, numerous modifications and variations of the present invention are possible in light of the teachings herein. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

The invention claimed is:

1. A sling implant system for treating a pelvic condition, comprising:

a sling implant having a support portion and one or more end anchors;

a needle delivery device having a handle body and a needle, wherein the needle includes a distal end portion adapted for selective engagement with the one or more end anchors of the sling implant;

an elongate sheath having a proximal end and a distal end, and adapted to at least partially shroud a length of the needle, with the proximal end housed within the handle body; and

an actuation mechanism having an actuator and at least one cam mechanism housed within the handle body and in operable communication with the elongate sheath, with the actuator including a barrel portion moveable in and out of the handle body such that activation of the actuator operably rotates the sheath about the needle such that the sheath does not move distally, such that the distal end of

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the elongate sheath rotatably abuts the one or more anchors to deploy the one or more anchors from the distal end portion.

2. The system of claim **1**, wherein the one or more end anchors include an end anchor on each end of the sling implant.

3. The system of claim **1**, wherein the one or more end anchors include extending anchor tines.

4. The system of claim **3**, wherein the elongate sheath includes a barb guard adapted to abut against the extending anchor tines.

5. The system of claim **1**, wherein the elongate sheath includes an angled end surface adapted to engage with the one or more anchors such that rotation of the elongate sheath forces the one or more anchors from the distal end portion of the needle.

6. The system of claim **1**, wherein the actuator is a pushable button in operable communication with the at least one cam mechanism and rotatable sheath.

7. The system of claim **1**, wherein the needle is curved.

8. The system of claim **1**, wherein the needle is straight.

9. The system of claim **1**, wherein the one or more anchors include at least one internal lumen protrusion and the distal end portion of the needle includes a corresponding mating feature to facilitate snap engagement of the one or more anchors with the distal end portion.

10. The system of claim **9**, wherein the at least one internal lumen protrusion includes two opposing internal lumen protrusions.

11. An implant system for treating a pelvic condition, comprising:

sling implant having a support portion and end tissue anchors;

a needle delivery device having a handle housing and a needle, wherein the needle includes a distal tip adapted for selective engagement with at least one of the end tissue anchors;

an elongate sheath having a proximal tip shrouded and rotatable within the handle housing, a distal tip, and adapted to at least partially shroud a length of the needle; and

an actuation mechanism shrouded within the handle housing and having an actuator in operable communication with the elongate sheath, and including a shaft adapted to traverse in and out of the handle housing, such that activation of the actuator operably rotates the sheath about the needle without moving the sheath distally, such that the distal tip of the elongate sheath rotatably abuts at least one of the end tissue anchors to facilitate deployment.

12. The system of claim **11**, wherein the end tissue anchors each include extending anchor tines.

13. The system of claim **12**, wherein the elongate sheath includes a barb guard adapted to abut against the extending anchor tines.

14. The system of claim **11**, wherein the elongate sheath includes an angled end surface adapted to engage with at least one of the end anchors such that rotation of the elongate sheath forces at least one of the end anchors from the distal tip of the needle.

15. The system of claim **11**, wherein the actuator is a pushable button in operable communication with the rotatable sheath.

16. The system of claim **11**, wherein the needle is curved.

17. The system of claim **11**, wherein the needle is straight.

18. The system of claim **11**, wherein at least one of the end anchors includes at least one internal lumen protrusion and

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the distal tip of the needle includes a corresponding mating feature to facilitate snap engagement of the at least one end anchor with the distal tip.

19. The system of claim **11**, further including a second needle delivery device adapted to engage with one of the end anchors.

20. The system of claim **11**, wherein the actuation mechanism further includes a cam mechanism adapted to operably facilitate the rotation of the rotatable sheath about the needle.

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